

K070489



**HEARTWAY MEDICAL PRODUCTS CO.,LTD.**

NO.6, ROAD 25, TAICHUNG INDUSTRIAL PARK, TAICHUNG, TAIWAN R.O.C. 408

TEL: 886-4-23580357 (Sales) · 23583232 (Rep) FAX: 886-4-23590786

Web: www.heartway.com.tw

E-mail: sales@heartway.com.tw



MAR 14 2007

**“ 510(k) SUMMARY ”**

Submitter's Name: **HEARTWAY Medical Products Co., Ltd.**

No.6, Road 25, Taichung Industrial Park, Taichung, 408, Taiwan, ROC

Date summary prepared:

February 13, 2007

Device Name:

Proprietary Name: HEARTWAY Power Tilt Seating System Power Chair,  
P16RT

Common or Usual Name: POWERED WHEELCHAIR

Classification Name: POWERED WHEELCHAIR, Class II,  
21 CFR 890.3860

Indications for Use:

The device is intended for medical purposes to provide mobility to persons restricted to a seated position.

Description of the device:

The HEARTWAY Power Tilt Seating System Power Chair, P16RT is an indoor / outdoor electric scooter that is battery operated. It has a base with four-wheeled with a seat, armrests, and a front basket. The movement of the scooter is controlled by the rider who uses hand controls located at the top of the steering column. The device can be disassembled for transport and is provided with an onboard battery charger.

Performance Testing:

EMC Report ANSI / RESNA WC/Vol.2-1998, CISPR 11: 1990, EN61000-3-2: 1995, IEC61000-3-3: 1995 (Electrically powered wheelchairs, scooters, and their chargers – requirements and test methods)

Legally marketed device for substantial equivalence comparison:

**FORYOU POWERED WHEELCHAIR, FC-100 (K061693)**



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# HEARTWAY

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### Summary for substantial equivalence comparison:

The intended use between the two devices is the same. Mainframes materials of the two devices all meet the strength and fatigue tests and they use the same material aspects. The suspension of cross brace, footplates, armrest type, and the warranty are all the same. The back upholstery material is also the same fabric and passed the resistance ignition test. Especially the electronic systems between two devices are the same suppliers, and all passed by the UL certificated, for instance the electronic controller, batteries, and the competent switches and switching power supplies. Thus the same safety level for the two devices is assured.

The major differences existing are the overall dimensions, maximum speed, cruising range, the incline degrees, and special designed for the power tilt seating system are differences between the two devices. The overall appearance differences are not safety aspect. So the new device is substantially equivalent to the predicate devices in this aspect.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Heartway Medical Products Co., Ltd.  
% ROC Chinese-European  
Industrial Research Society  
Dr. Ke-Min Jen  
Official Correspondent  
No. 58, Fu-Chiun Street  
Hsin-Chu City, Taiwan  
Republic of China

MAR 14 2007

Re: K070489

Trade/Device Name: Heartway Power Tilt Seating System Power Chair, P16RT  
Regulation Number: 21 CFR 890.3860  
Regulation Name: Powered wheelchair  
Regulatory Class: Class II  
Product Code: ITI  
Dated: February 5, 2007  
Received: February 14, 2007

Dear Dr. Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

Page 2 – Dr. Ke-Min Jen

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Mark N. Melkerson".

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510 (K) Number ( If Known ):   K  

Device Name: HEARTWAY Power Tilt Seating System Power Chair,  
P16RT

Indications for Use:

The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.

Prescription Use \_\_\_\_\_

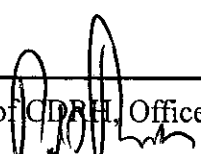
AND/OR

Over-The-Counter Use   √  

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of  Office of Device Evaluation (ODE)

**(Division Sign-Off)**

**Division of General Restorative,  
and Neurological Devices**

510(k) Number

  K070489  

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